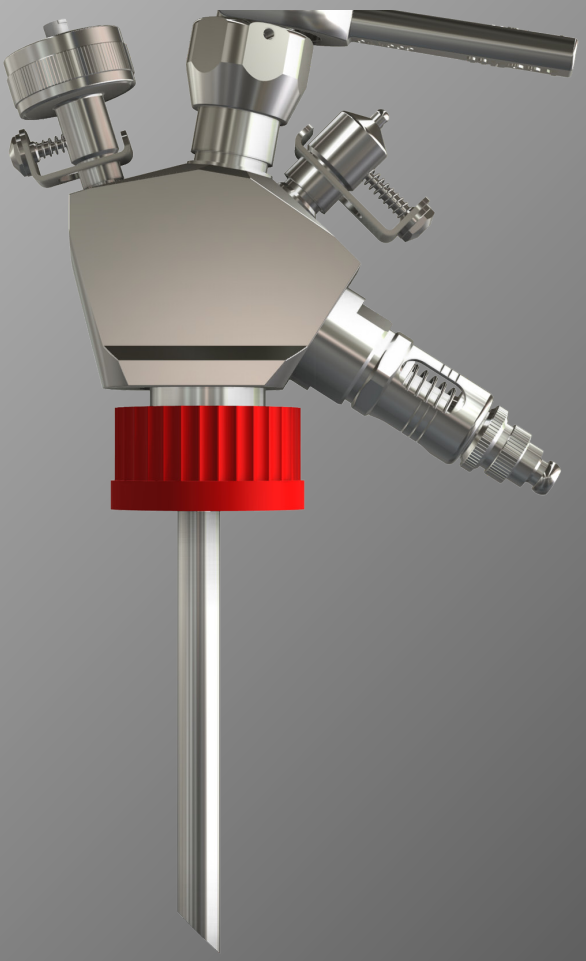
KEOFITT®

WORLD LEADERS IN STERILE SAMPLING™

ASEPTIC SAMPLING SYSTEM | Item no. 260001

User Manual



SOME PEOPLE WOULDN'T GAMBLE WITH THEIR SAMPLE™

INTRODUCTION:

MANUFACTURER: Keofitt A/S,
Lumbyvej 11H
5000 Odense C
Denmark

TYPE: Aseptic system, item no. 260001
YEAR OF INTRODUCTION: 1998
YEAR OF REVISED DESIGN: 2009

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PRESENTATION

The Keofitt Aseptic system enables the user to take a truly representative aseptic sample. The aseptic system protects the sample against airborne contamination, while taking the sample and in transportation.
The aseptic system is compatible with all small and medium sized sampling valves.

The Keofitt aseptic system is based on Keofitt's guarantied high quality, microbiologically safe valve design.

The aseptic system is used in a wide range of industries, such as breweries, food and the pharmaceutical and biotechnological industries.

ASEPTIC SYSTEM FUNCTION

The aseptic system is designed to regularly take representative samples in the production process. The aseptic system is therefore designed so that effective cleaning, sterilisation and sampling can be carried out regularly without interrupting the production process.

Sterilisation is carried out by supplying steam through the aseptic systems hose piece. It is the perfect, hygienic design of the aseptic system that enables absolute sterilisation. The Keofitt aseptic system is based on the Keofitt valve design and according to an EHEDG-based test carried out by the Biotechnological Institute in Denmark, the valve is sterilised after just 1 minute's supply of steam at a pressure of 2 bar (121°C).

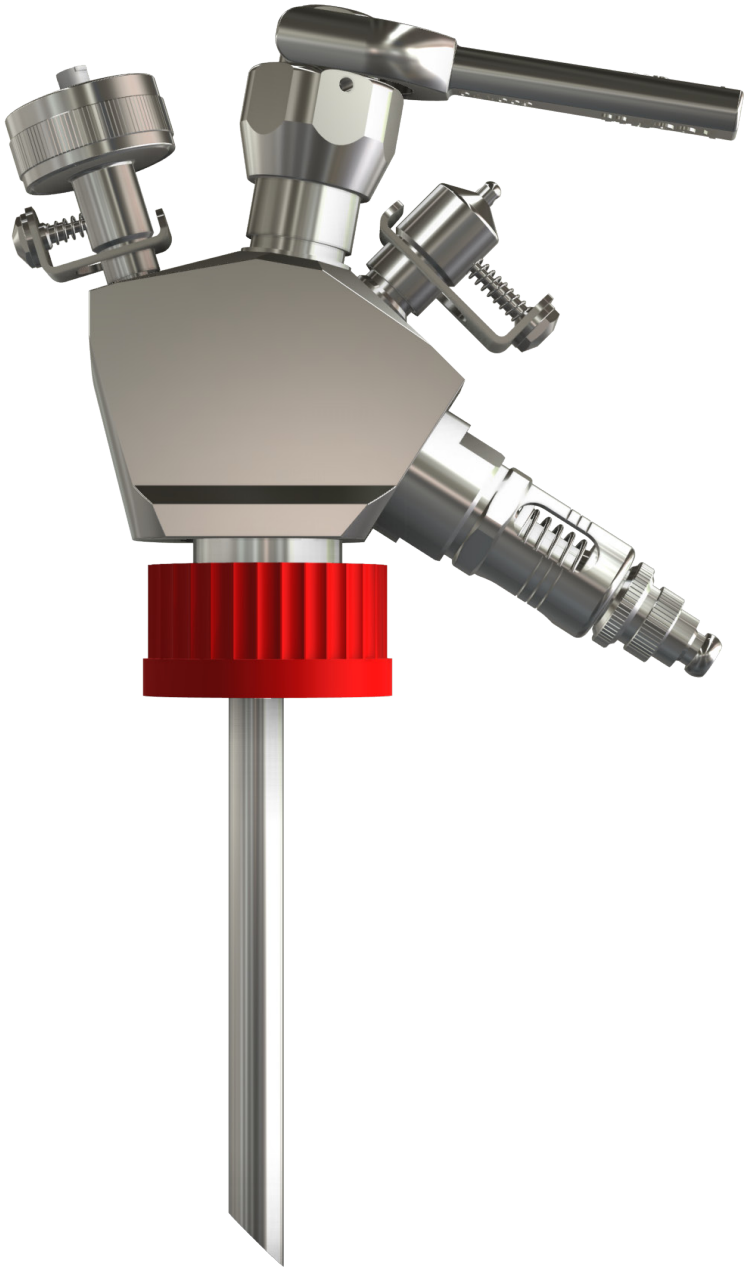
WARNING!

- The Aseptic system will become hot and emits steam while sterilizing. Use gloves and eye protection while operating.
- While steam sterilizing the steam will be let trough the pressure relief valve. Take care while operating. It is possible to connect a drain hose to the pressure relief valve and lead the steam to a safe drainage.
- Do not open the valve head while sterilizing with steam. As it lets the steam in the bottle and will damage the sterile filter. There is also a risk of the bottle exploding due to too high pressure.
- The aseptic system is designed for use in working conditions of up to 1 bar and temperatures of up to 121°C. It is therefore important to be aware that the glass bottle will explode at higher pressure. Take care while operating the aseptic system – use gloves and eye protection.
- It is important that the filter is changed after every use as there otherwise is the risk that the filter is blocked and pressure build up in the bottle.

IMPORTANT!

- It is recommended to use a sterile filter with a pore size of 0,45 µm.
- The system is designed to be used with PP bottles (type Krones or similar).
- If product is heat sensitive let the aseptic system cool down before sampling.
- Do not remove steam hose from the valve until after the sample has been taken.
- Assembling the valve head in closed position can damage and tear the membrane.

ITEM 260001, ASEPTIC SAMPLING SYSTEM



TECHNICAL DATA

Material

Steel parts:	AISI 304 / 316 / 316L (1.4404)
Membranes:	PTFE (FDA approved)
O-rings:	Silicone/EPDM
Gasket:	PTFE/Silicone

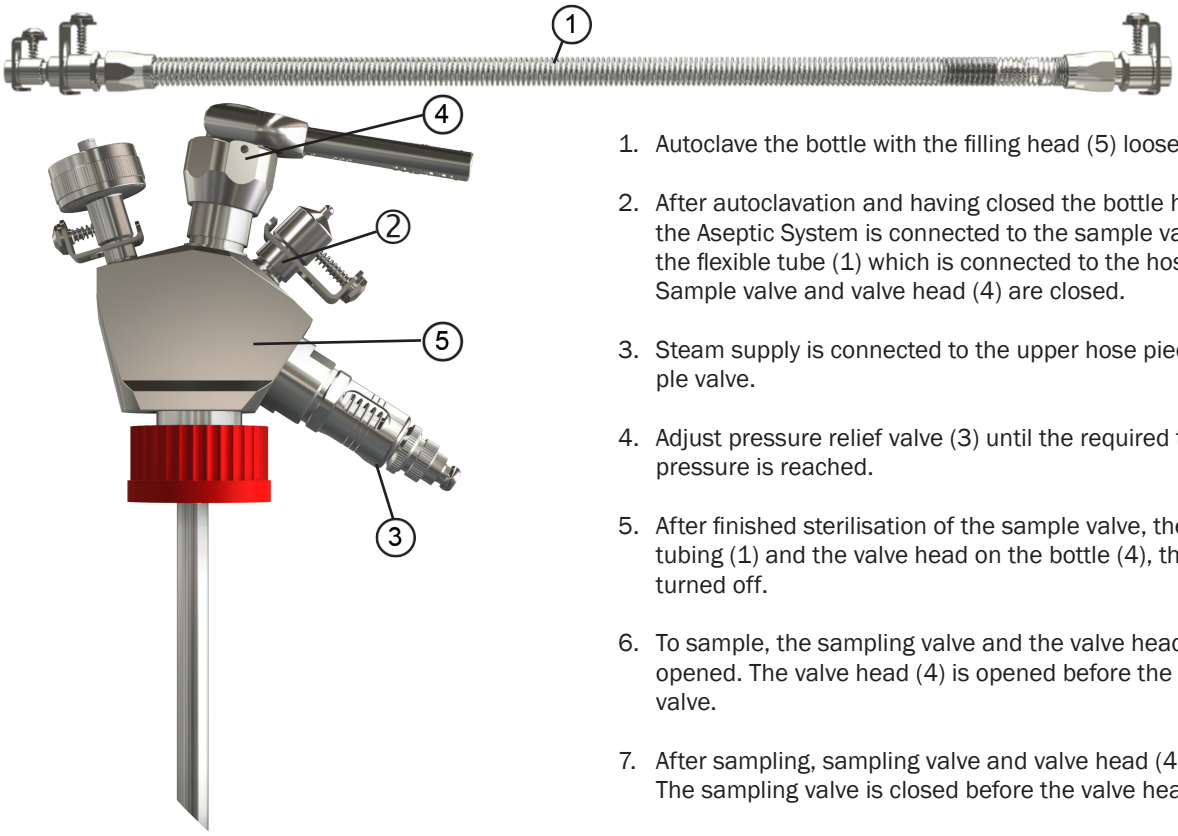
Pressure

Max steam pressure:	2 bar(g) / 29 psi(g)
Max bottle pressure:	1,2 bar(g) / 18 psi(g)

Net weight: 1,7 kg / 3,75 lb

HOW TO USE

SAMPLING



1. Autoclave the bottle with the filling head (5) loosely mounted.
2. After autoclavation and having closed the bottle hermetically, the Aseptic System is connected to the sample valve by using the flexible tube (1) which is connected to the hose piece (2). Sample valve and valve head (4) are closed.
3. Steam supply is connected to the upper hose piece of the sample valve.
4. Adjust pressure relief valve (3) until the required temperature/ pressure is reached.
5. After finished sterilisation of the sample valve, the connecting tubing (1) and the valve head on the bottle (4), the steam is turned off.
6. To sample, the sampling valve and the valve head (4) are opened. The valve head (4) is opened before the sampling valve.
7. After sampling, sampling valve and valve head (4) are closed. The sampling valve is closed before the valve head (4).
8. Repeat steps 3 – 5. The Aseptic System, now containing the sample, is ready for transport to the laboratory.
9. Place the aseptic system in a sterile bench, detach the bottle and remove it from the aseptic system. Now there is access to the sample.

IMPORTANT

- Do not remove steam hose from valve until after the sample has been taken.
- If the product is heat sensitive let the aseptic system cool down before sampling.

WARNING

- The Aseptic system becomes hot and emits steam while sterilizing. Use gloves and eye protection while operating.
- The aseptic system is designed for use in working conditions of up to 1 bar and temperatures of up to 121°C. It is therefore important to be aware that the glass bottle will explode at higher pressure. Take care while operating the aseptic system and use gloves and eye protection.
- Do not use a filter that has been used before as this may cause pressure build up in the bottle and possible explosion.

STERILISATION

1. Cleaning takes place with system disassembled.
   a. Detach bottle
   b. Remove the filter unit and filter
   c. Open valve head, disassemble and remove from the aseptic system
   d. Remove steel cap from inlet
2. Wash all parts in washing machine or manually
3. Assemble all parts again
   a. Fasten the valve head in open position
   b. Attach the filter unit with a new sterile filter
   c. Loosely fasten a sampling bottle to the aseptic system
   d. Add one drop of water to the inlet before the steel cap is closed
4. Autoclave the assembled aseptic system
5. Close the valve head while the aseptic system is still in the autoclave, to avoid air contamination
6. Connect the aseptic system to the sampling valve with the PTFE tube
7. Open steam for sterilization of the valve. The steam will also sterilize the connection tube and areas inside of the aseptic system that have come in contact with air. The steam will be let through the pressure relief valve.
8. Close steam valve. But do not remove steam tube until after the sample has been taken.

WARNING!

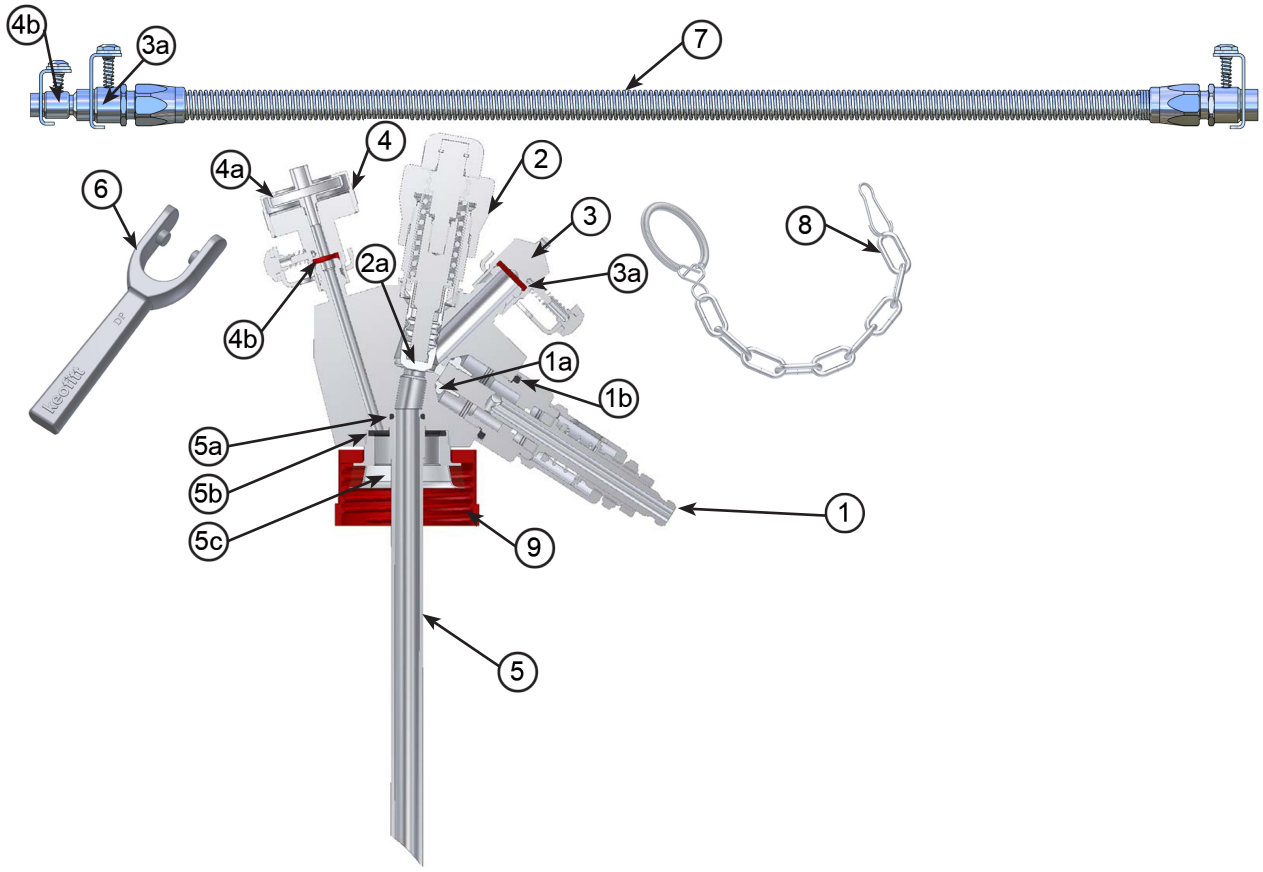
- While steam sterilizing the steam will be let through the pressure relief valve. Take care while operating. It is possible to connect a drain hose to the pressure relief valve and lead the steam to a safe drainage.
- Do not open the valve head while sterilizing with steam. That lets the steam in the bottle and will damage the sterile filter. There is also a risk of the bottle exploding due to too high pressure.

IMPORTANT!

- Assembling the valve head in closed position can damage and tear the membrane.
- Use saturated steam without condensation at max. 2 bar. At higher pressures the membrane can be damaged/split.

MAINTENANCE

Keofitt recommends to change the PTFE membrane once a year or as needed. The recommendation is based on 1-5 samples a day.
In the event of intensive sterilisation and cleaning it may be necessary to replace it more frequently.



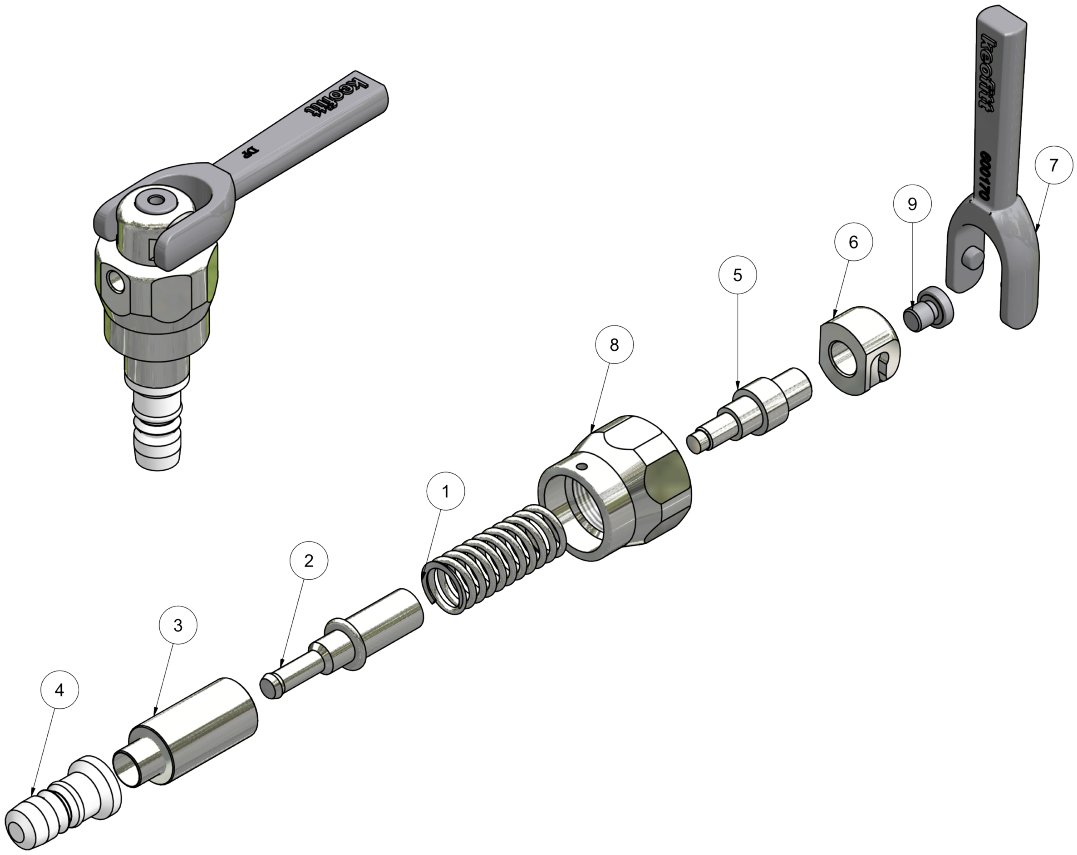
MAIN PARTS

Pos.	Qty.	Item	Material	Ident no.	Remark
1	1	Pressure relief valve, Aseptic System	-	260059	-
2	1	Valve Head W9 type Q (Teflon)	-	855543	Option EPDM or Silicone
3	1	Quick coupling st. st. plug for W9	316L, Silicone	800061	-
4	1	Snap clutch secure filter (Aseptic)	-	260081	-
5	1	Filling tube complete for 500ml	316L, Silicone	260170	-
6	1	Q-handle	316L	600170	-
7	1	Tube complete - length 500mm	PTFE, 316L, Silicone	550002	-
8	1	St. st. chain for Aseptic Sampling Valve		600063	-

SPARE PARTS

Pos.	Qty.	Item	Material	Ident no.	Remark
1a	1	Teflon plug for p.r.v.	PTFE (TFM1600)	260167	-
1b	1	O-ring 22,23 x 2,62	EPDM	260158	-
2a	1	Membrane Teflon for W9	PTFE (TFM1600)	850055	-
3a	3	O-ring 10,3 x 2,4	Silicone	800830	-
4a	1	Sterile filter for Aseptic System	-	260122	0,45
4b	2	O-ring 5,3 x 2,4	Silicone	400830	-
5a	1	O-ring 9,50 x 2,0	EPDM	260156	-
5b	1	O-ring 24,6 x 2,4	EPDM	260159	-
5c	1	Gasket	PTFE/Silicone	260115	-
9	1	Cap	-	260116	-

VALVE HEAD FOR ASEPTIC SAMPLING SYSTEM. ITEM NO. 855543



TECHNICAL DATA

Material (process contact)
- Membrane PTFE

Material (without process contact)
- Steel parts AISI 316L (1.4404), AISI 304 (1.4301)

Temperature, process 1°C - 150°C / 34°F - 302°F

Pressure, process 6 bar / 87 psi

Net weight
- 0,295 kg / 0,65 lb

PARTS

Pos.	Qty.	Item	Material	Ident no.	Remark
1	1	Spring for H+K+Q W9	AISI 316L	600411	1.4404
2	1	Valve stem H W9	AISI 316L	600340	1.4404
3	1	Bushing for W9	AISI 303	600149	1.4305
4	1	Membrane Teflon W9	PTFE (TFM1600)	850055	
5	1	Upper stem Q W9	AISI 316L	600169	1.4404
6	1	Plug for Q handle W9	AISI 316L	600168	1.4404
7	1	Handle for Q head W9	AISI 316L	600170	1.4404
8	1	Hex nut H+K+Q W9	AISI 316L	850151	1.4404
9	1	Screw for M4/W9 W head		600178	

INSTRUCTIONS ON REPLACING PTFE MEMBRANE

1. Open valve.
2. Remove the valve head from the valve body.
3. Push the membrane upwards until the tool for membrane fits under it.
4. Insert tool for membrane, between the membrane and the bushing.
5. Close valve head.
6. Now the membrane is loosened from the valve head and can be replaced.

To attach new membrane to valve head.

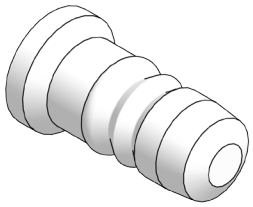
7. Set the valve head to closed position.
8. Place the new membrane on valve head.
9. Mount the membrane bushing with the new Teflon membrane by pressing the membrane with your hand until it clicks.
10. Set the valve head in open position.
11. Insert the valve head into the valve body.
12. Close valve head.

IMPORTANT

- Once the membrane has been removed from the valve head the click system in the membrane might be damaged. Therefore the membrane might be unsafe for further use and it is recommended not to use the membrane again.
- Do not use hammer or other tool that might scratch the surface of the membrane.

Tool nr.	*Type of valve*
300255	*I40, I52 and W15*
400255	*M4*
600255	*W9*
870255	*W25*

PTFE MEMBRANE - ITEM NO. 850055

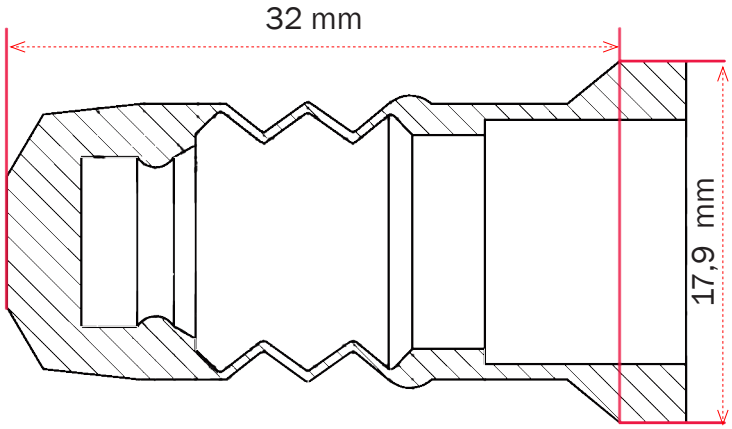


Technical Specification

• Type:		AF1012 PTFE
• Colour:		White
• Temperature range		- 200 - +200ºC
• Ball hardness		29 N/mm2
• Tensile strength	DIN53455	35 N/mm2
• Elongation at break	DIN53455	350%
• Density	DIN 53479	2.17 g/cm3
• Shore D	DIN 53505	57
• Thermal conductivity	W/m.k DIN 57572	0.25 - 0.5 mm
• Expansion coefficient	DIN 52612	9-12 x 10^{-5} K^{-1}
• Friction coefficient		very low (<0.1)
• Flammability	Inflammable UL 94V0	
• Chemical resistance	*	
• Food safe	Yes (FDA**)	
• Temp. max.		150°C
• Steam pressure max.		2 bar/29 psi
• Process pressure		1-6 bar/14-87 psi

Keofitt recommends to change the PTFE membrane once a year or as needed. The recommendation is based on 1-5 samples a day.

* Is not attacked by common chemicals, with the exception of strongly oxidising acids.
**FDA approved compound according to Code of Federal Regulations Title 21 - § 177.1550



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